**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

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| GUARDANT HEALTH, INC., | ) | |
| | ) | |
| Plaintiff, | ) | |
| | ) | C.A. No. _____ |
| v. | ) | |
| | ) | **JURY TRIAL DEMANDED** |
| TEMPUS AI, INC., | ) | |
| | ) | |
| Defendant. | ) | |

**PLAINTIFF'S COMPLAINT FOR DECLARATORY RELIEF**

Plaintiff Guardant Health, Inc. ("Guardant") files this Complaint for declaratory relief against Defendant Tempus AI, Inc. ("Tempus") and alleges as follows:

**OVERVIEW OF THE ACTION**

1. Guardant brings this action for declaratory relief per 28 U.S.C. § 2201 and Rules 8 and 57 of the Federal Rules of Civil Procedure. Guardant seeks a judicial determination of the respective rights, duties, and obligations of the parties because a dispute has arisen about the propriety of certain advertisements distributed by Guardant. Guardant's advertisements reflect the performance of Guardant's liquid biopsy assay, Guardant360, and Tempus's assay, Tempus xF+. This action is necessitated by Tempus's sending of a cease-and-desist letter to Guardant on January 13, 2025, erroneously claiming Guardant's advertisements regarding Tempus's inferior product were false or misleading.

**THE PARTIES**

2. Guardant is a corporation organized and existing under the laws of the state of Delaware, having its principal place of business at 3100 Hanover Street, Palo Alto, CA 94034.

3. Tempus is a corporation organized and existing under the laws of the state of Delaware. Its principal place of business is 600 West Chicago Avenue, Suite 510, Chicago, Illinois 60654.

## JURISDICTION AND VENUE

4. The United States District Court for the District of Delaware has original jurisdiction over this case under 28 U.S.C. § 2201 and 28 U.S.C. § 1331 because the underlying claim involves false advertising under the Lanham Act.

5. Venue is also proper under 28 U.S.C. §1391(b)(3) as the parties are subject to the Court's personal jurisdiction with respect to this action since each party is already a party to another lawsuit pending in Delaware.

6. This Court is authorized to grant declaratory judgment under the Declaratory Judgment Act, 28 U.S.C. § 2201, per Rule 57 of the Federal Rules of Civil Procedure.

7. This Court has personal jurisdiction over Tempus because Tempus is subject to general and specific jurisdiction in the state of Delaware. Tempus is subject to personal jurisdiction at least because Tempus is a Delaware corporation and resides in this District. Tempus has made certain minimum contacts with Delaware such that the maintenance of this suit does not offend traditional notions of fair play and substantial justice.

8. The exercise of personal jurisdiction comports with Tempus's right to due process because, as described above, Tempus has purposefully availed itself of the privilege of Delaware corporate laws such that it should reasonably anticipate being haled into court here.

## THE PARTIES' DISPUTE

9. Guardant is a leading precision oncology company dedicated to helping conquer cancer with data obtained through its proprietary blood tests. Guardant was founded over a decade ago by Helmy Eltoukhy, Ph.D., and AmirAli Talasaz, Ph.D., pioneers in DNA sequencing and

cancer diagnostics. Since its inception, Guardant has focused its expertise on the development of groundbreaking liquid biopsy cancer tests, including Guardant360® CDx, the first FDA-approved liquid biopsy test. To date, over 500,000 patient samples have been analyzed using Guardant's tests.

10. A liquid biopsy is the sampling and analysis of non-solid biological tissues, such as a patient's blood. It is distinct from a conventional biopsy, which involves the removal of tissue for examination and is often conducted surgically. All cells in the human body contain DNA. When a person's organ or tissues suffer from disease such as cancer, the DNA in the cells making up the organ or tissue may contain biomarkers that indicate the presence of the disease. Traditionally, a biopsy would need to extract cells from a particular organ or tissues of interest. The DNA from those cells would then be analyzed for biomarkers.

11. But pieces of DNA originating from cells in many different organs and tissues also circulate freely in the human bloodstream. These DNA fragments circulating in the bloodstream are known as "cell-free DNA" or "cfDNA." A simple, non-invasive blood draw can capture cell-free DNA originating from cells in many different organs and tissues all at once. That DNA can then be analyzed for relevant biomarkers indicating the presence of disease. But using cell-free DNA in the bloodstream to look for biomarkers raises substantial complexity and problems. A traditional biopsy provides a very large sample of DNA from a particular type of cell. With cell-free DNA, very small numbers of DNA fragments originating from the cells of interest may be present, mixed in with very large numbers of DNA fragments from many other cells.

12. Guardant is a pioneer in the field and solved many of the problems critical to unlocking the use of cell-free DNA to detect cancer and other disease in the blood. For example, Guardant was one of the first companies to commercialize a comprehensive liquid biopsy test to

identify genomic biomarkers. Guardant's liquid biopsy technology enables patients, including those who are ineligible for traditional tissue biopsies, to obtain detailed genomic information about their cancer. Guardant's technology also allows patients to be screened for a large number of potential cancers or diseases that may be present in different parts of the body, all with a simple blood draw.

13. For example, the Guardant360® CDx test is a liquid biopsy test that provides clinically actionable information from a routine blood draw taken from cancer patients. From the extracted cell-free DNA, the test sequences a panel of genes commonly mutated in cancer and detects genetic aberrations such as single nucleotide variants, indels (insertions or deletions of nucleotides), gene fusions, and copy number variants.

14. In addition to the FDA-approved Guardant360® CDx test, Guardant currently offers six other tests: the Guardant360® laboratory developed test (LDT), the Guardant360 Response™, Guardant360 TissueNext™, Guardant Infinity™, Guardant Reveal™, and Shield™ tests. These tests span the cancer care continuum, including early cancer screening, treatment selection, and residual disease and recurrence monitoring.

15. Guardant's liquid biopsy technology has several additional advantages when compared to traditional tissue biopsies. Traditional tumor-based genotyping tests are limited in the number of genes interrogated, require invasive biopsies, and often take upwards of 15 days before results are generated. Guardant's liquid biopsies are less painful and do not require hospital services. This technology is also less expensive and generates results in a shorter period of time, often in less than a week. Further, cfDNA samples allow for the detection of mutations that may be missed by a tissue biopsy sample.

16. Guardant's technology is built on a series of cutting-edge innovations that Guardant's scientists developed over many years and at great cost through an extensive research and development program. Those innovations are protected by over 95 patents issued by the United States Patent and Trademark Office, including the Patents-in-Suit. These patents were issued in recognition of the novelty and usefulness of Guardant's patents.

17. Tempus was founded in 2015. Since its inception, Tempus has capitalized on Guardant's pioneering efforts to develop copy-cat cell-free DNA liquid biopsy tests. Tempus was formerly known as Tempus Labs, Inc.

18. Tempus makes, markets, and uses liquid biopsy panels in ways that compete with Guardant's patented products.

19. One such category of liquid biopsy panels includes a product known as Tempus xF+.

20. Tempus xF+ is inferior to Guardant's patented Guardant360, and Guardant developed a recent advertising campaign reflecting the performance of Guardant's and Tempus's assays.

21. On January 13, 2025, Tempus's Executive Vice President and General Counsel, Andrew Polovin, sent a letter to John Saia, Guardant's Chief Legal Officer. Mr. Polovin's letter claimed Guardant's advertising comparing Guardant360 with Tempus xF+, was false and misleading, implicating potential claims under the Lanham Act.

22. Guardant disputes the erroneous claims in Tempus's letter.

**FIRST COUNT**
**(Declaratory Relief)**

23. Guardant repeats and re-alleges the foregoing paragraphs as if set forth specifically herein.

24. Guardant asserts that the advertising surrounding its Guardant360 product, and the comparisons between Guardant's patented product and Tempus's product, Tempus xF+, are not false nor misleading based on publicly available information on Tempus' products.

25. On information and belief, and based on Tempus's January 13, 2025, letter to Guardant, Tempus alleges Guardant's advertising for its Guardant360 product, including the comparisons to Tempus's xF+ product, is false and misleading.

26. An actual controversy has arisen and now exists between Guardant, on the one hand, and Tempus, on the other hand, with regard to the rights, duties, and obligations of Guardant regarding its Guardant360 product, including the comparisons to Tempus's xF+ product.

27. Due to the actual and present controversy described above, Guardant requests a judicial declaration of the rights, duties, and obligations, of Guardant regarding its Guardant360 product, including the comparisons to Tempus's xF+ product.

## PRAYER FOR RELIEF

WHEREFORE, Guardant prays for and respectfully requests:

a. That this Court enter a judgment determining and declaring that Guardant's advertising for its Guardant360 product is not false or misleading; and Guardant's advertising comparing its Guardant360 product with Tempus's xF+ is not false or misleading;

b. Award Guardant its costs; and

c. Grant such further relief as the Court deems just and proper.

## DEMAND FOR JURY TRIAL

Per Rule 38(b) of the Federal Rules of Civil Procedure, Guardant demands a trial by jury in this action for all issues triable by a jury.

Respectfully submitted,

POTTER ANDERSON & CORROON LLP

By: */s/ David E. Moore*

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